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ATTORNEY DOCKET: P6191

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rolland-Yves Mauvernay)

Serial No.: 09/807,586)

Filed: April 12, 2001)

For: OXALIPLATINUM)
PREPARATION PACKAGING)

Examiner: Unknown)

Group Art Unit: Unassigned)

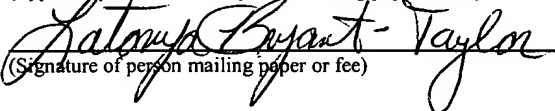
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Date of Deposit August 15, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

LaTonya Bryant-Taylor

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COMMISSIONER FOR PATENTS
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U.S. PATENT & TRADEMARK OFFICE
WASHINGTON, D.C. 20231

RESPONSE TO NOTIFICATION OF A DEFECTIVE RESPONSE

Dear Sir:

This is in response to the Notification of a Defective Response which was mailed July 20, 2001. The Notification sets a deadline for response expiring August 20, 2001.

REMARKS

The Notification of a Defective Response (copy enclosed) indicates that Applicant's response filed July 11, 2001, in response to the Notification of Missing Requirements, failed to include the translation of the International Application into English.

Applicant(s): Rolland-Yves Mauvernay
Serial No.: 09/807,586

Applicant respectfully submits that the translation was provided at the time Applicant originally entered the U.S. National Phase. In particular, the application as filed April 12, 2001 included a translation of the International Application, as well as a translation of amended specification page 2 and claim pages 9 and 10. Further, the original application included Verification of the English Translation.

In support of the foregoing, Applicant submits herewith the following:

1. Copy of Certification Under 37 CFR 1.10 regarding entering the U.S. National Phase;
2. Copy of the Transmittal Letter, which includes a checkbox for the English Translation (item number 6), and the Verification of English Translation and translation of amended specification page 2, and claim pages 9 and 10 (item number 19) (2 pages);
3. Copy of the cover page of the published International Application, including an English Translation of the abstract
4. Copy of the English Translation and Verification of English Translation; and
5. Copy of the returned postcard date-stamped and confirming that the U.S. Patent Office received the English Translation.

In view of the foregoing, Applicant respectfully submits that the foregoing is fully responsive to the Notification of a Defective Response, and that no fee is required in connection with the foregoing.

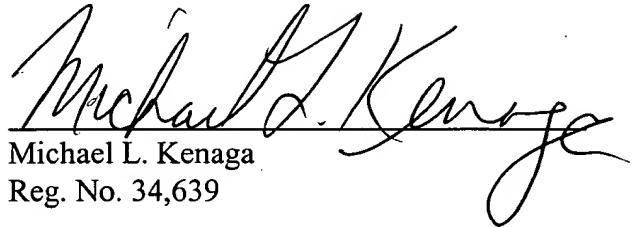
ATTORNEY DOCKET: P6191

PATENT

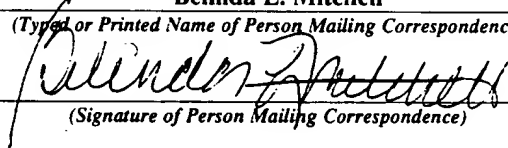
Applicant(s): Rolland-Yves Mauvernay
Serial No.: 09/807,586

Please feel free to telephone the undersigned in the event you have any questions or comments.

Respectfully submitted,


Michael L. Kenaga
Reg. No. 34,639

Piper Marbury Rudnick & Wolfe
P.O. Box 64807
Chicago, IL 60664-0807
Phone: (312) 368-4000
Fax: (312) 236-7516

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)			Docket No. P-6191
Applicant(s): MAUVERNAY, Rolland-Yves			
Serial No.	Filing Date 12 April 2001	Examiner	Group Art Unit
Invention: OXALIPLATINUM PREPARATION PACKAGING			
<p>I hereby certify that this <u>Utility Patent Application (National Phase Entry)</u> <i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231 on <u>April 12, 2001</u> <i>(Date)</i></p> <div style="text-align: right;"><p>Belinda L. Mitchell <i>(Typed or Printed Name of Person Mailing Correspondence)</i></p><p> <i>(Signature of Person Mailing Correspondence)</i></p><p>EL178952483US <i>("Express Mail" Mailing Label Number)</i></p></div>			
<p>Note: Each paper must have its own certificate of mailing.</p>			

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

P-6191

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

INTERNATIONAL APPLICATION NO.
PCT/IB99/01670INTERNATIONAL FILING DATE
13 October 1999PRIORITY DATE CLAIMED
14 October 1998

TITLE OF INVENTION

OXALIPLATINUM PREPARATION PACKAGING

APPLICANT(S) FOR DO/EO/US

Rolland-Yves MAUVERNAY

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☒ Certificate of Mailing by Express Mail
19. ☒ Other items or information:

Cover Page of published PCT International Application No. PCT/IB99/01670
Verification of English Translation of International Application
Translation of amended Specification, page 2 and claims pages 9 and 10
Substitute Drawing Sheet numbers 1 through 6, containing Figures 1-7
Return Receipt Postcard

20. The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

☒ Search Report has been prepared by the EPO or JPO \$860.00

☐ International preliminary examination fee paid to USPTO (37 CFR 1.482)

☐ No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))

☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO

☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)

ENTER APPROPRIATE BASIC FEE AMOUNT =

Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). ☐ 20 ☐ 30

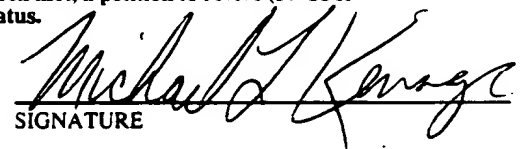
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	9 - 20 =	0	x \$18.00	\$0.00
Independent claims	1 - 3 =	0	x \$80.00	\$0.00
Multiple Dependent Claims (check if applicable). <input checked="" type="checkbox"/>				\$270.00
TOTAL OF ABOVE CALCULATIONS =				\$860.00
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>				\$0.00
SUBTOTAL =				\$1,130.00
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30 +				\$0.00
TOTAL NATIONAL FEE =				\$1,130.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL FEES ENCLOSED =				\$1,130.00
				Amount to be: refunded \$
				charged \$

- ☐ A check in the amount of _____ to cover the above fees is enclosed.
- ☒ Please charge my Deposit Account No. **18-2284** in the amount of **\$1,130.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **18-2284** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Michael L. Kenaga
PIPER MARBURY RUDNICK & WOLFE
P.O. Box 64807
Chicago, Illinois, 60664-0807


SIGNATURE

Michael L. Kenaga

NAME

34,639

REGISTRATION NUMBER

April 12, 2001
DATE

IN THE MATTER OF INTERNATIONAL
PATENT APPLICATION No. PCT IB99/01670
FILED ON OCTOBER 13, 1999 IN THE NAME
OF DEBIOPIARM S.A

and

IN THE MATTER OF AN APPLICATION
FOR A PATENT IN UNITED STATES
CORRESPONDING THERETO

VERIFICATION OF ENGLISH TRANSLATION
OF INTERNATIONAL APPLICATION

I, Cyra NARGOLWALLA of CABINET PLASSERAUD - 84 rue d'Amsterdam,
75009 PARIS, France, declare that I am well acquainted with the
English and French languages and that the English translation,
submitted herewith, of the above-identified International Application,
which was filed in Switzerland, is a true and accurate translation.

Date: April 11, 2001

Signature:



Cette préparation pharmaceutique a été conservée dans des flacons en verre neutre pour usage pharmaceutique sous atmosphère d'un gaz inerte. Cependant, de tels flaconnages, s'ils sont appropriés pour la conservation sur une longue période de la préparation pharmaceutique, ne le sont pas pour contenir cette préparation lors d'une administration par perfusion.

Lors d'opérations de perfusion de préparations liquides de complexes du platine autres que l'oxaliplatine tels que le cisplatine ou le carboplatine, on utilise des poches souples constituées d'un matériau à base de chlorure de polyvinyle (PVC).

Toutefois, et contrairement à ce qui a été observé pour des préparations liquides de cisplatine et de carboplatine, il s'est avéré que, du fait en particulier d'une sensibilité chimique plus accrue, les préparations pharmaceutiques d'oxaliplatine en solution aqueuse ne peuvent se trouver au contact de matériaux à base de PVC, ni être transportées et/ou conservées au sein de récipients, en particulier des poches souples, à base de ces matériaux.

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Le but de la présente invention est de mettre à disposition des préparations liquides pharmaceutiques d'oxaliplatine qui puissent être non seulement conservées au cours d'une longue période de temps sans qu'aucune perte de qualité ne puisse être constatée, mais également qui puissent être utilisées en particulier pour des opérations de perfusion sans qu'aucune opération de transvasement des préparations liquides pharmaceutiques ne soit à effectuer par le personnel soignant.

A cet effet, la présente invention concerne une poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine se trouvant sous forme liquide telle que définie à la

revendication 1. Les différentes variantes d'exécution sont telles que
définies aux revendications 2 à 9.

Revendications

- 1) Poche souple étanche à usage médical contenant une préparation
5 pharmaceutique d'oxaliplatine se trouvant sous forme liquide, caractérisée en ce que ladite poche souple est réalisée en matière plastique, à l'exclusion, pour ladite matière se trouvant au contact direct de ladite préparation pharmaceutique, d'un matériau à base de PVC.
- 10 2) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon la revendication 1, caractérisée en ce que l'enveloppe de ladite poche a une structure multicouche.
- 15 3) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine d'oxaliplatine selon l'une des revendications précédentes, caractérisée en ce que la solution liquide d'oxaliplatine se trouve au contact d'une couche interne de ladite
enveloppe constituée en un matériau polypropylène.
- 20 4) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon l'une des revendications précédentes, caractérisée en ce que la concentration en oxaliplatine de la préparation pharmaceutique est comprise entre 1 et 8 mg/ml.
- 25 5) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon la revendication 4, caractérisée en ce que ladite concentration est comprise entre 1 et 5 mg/ml.
- 30 6) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon l'une des revendications précédentes, caractérisée en ce que cette poche souple est constituée de deux feuilles soudées de matériau multicouche en feuille comprenant un

film de polyamide de l'acide 11-amino-un-décanoïque lié par l'une au moins de ses faces à un film de polypropylène au moyen d'un film de polyoléfine, les films de polypropylène formant la paroi interne de la poche souple étanche.

5

7) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon l'une des revendications précédentes, caractérisée en ce que cette poche souple est multi compartimentée.

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8) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon la revendication 7, caractérisée en ce que les multi compartiments sont définis de manière à permettre le dosage d'une préparation prête à l'emploi.

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9) Poche souple étanche à usage médical contenant une préparation pharmaceutique d'oxaliplatine selon l'une des revendications précédentes, caractérisée en ce que cette solution présente un pH de 4,5 à 6, une teneur en oxaliplatine dans la préparation d'au moins 95 % de la teneur initiale, ainsi qu'un aspect limpide incolore exempt de précipité après

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conservation pendant une durée pharmaceutiquement acceptable.

PCT

ORGANISATION MONDIALE DE LA PROPRIÉTÉ INTELLECTUELLE
Bureau international

DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITE DE COOPERATION EN MATIERE DE BREVETS (PCT)

(51) Classification internationale des brevets ⁷ : A61K 31/28, 33/24, 9/08	A2	(11) Numéro de publication internationale: WO 00/21527 (43) Date de publication internationale: 20 avril 2000 (20.04.00)
(21) Numéro de la demande internationale: PCT/IB99/01670 (22) Date du dépôt international: 13 octobre 1999 (13.10.99) (30) Données relatives à la priorité: 2067/98 14 octobre 1998 (14.10.98) CH (71) Déposant (pour tous les Etats désignés sauf US): DEBIO- PHARM S.A. (CH/CH); 17, rue des Terreaux, CH-1000 Lausanne 9 (CH). (72) Inventeur, et (75) Inventeur/Déposant (US seulement): MAUVERNAY, Rol- land-Yves (CH/CH); 17, rue des Terreaux, CH-1000 Lau- sanne 9 (CH).	(81) Etats désignés: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, brevet ARJPO (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), brevet eurasiatique (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Publiée Sans rapport de recherche internationale, sera republiée dès réception de ce rapport.	
(54) Title: OXALIPLATINUM PREPARATION PACKAGING (54) Titre: CONDITIONNEMENT D'UNE PREPARATION D'OXALIPLATINE (57) Abstract <p>The invention concerns a liquid pharmaceutical preparation of oxiplatinum packaged in a container, preferably in a sealed soft bag for medical use. The liquid preparation of oxiplatinum can advantageously be presented in the form of a bag with several compartments containing doses of a ready-to-use solution.</p> (57) Abrégé <p>La présente invention se rapporte à une préparation pharmaceutique liquide d'oxaliplatine conditionnée en récipient, de préférence dans une poche souple étanche à usage médical. La préparation liquide d'oxaliplatine peut se présenter avantageusement sous la forme de poche multicompartimentée permettant le dosage d'une solution prête à l'emploi.</p>		

RECEIVED IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): MAUVERNAY, Rolland-Yves
Int'l Appn No. PCT/IB99/01670
Int'l Filing Date: October 13, 1999
For: OXALIPLATINUM PREPARATION PACKAGING
Our Docket: P-6191 (218728-109)

JC04 Rec'd PCT/PTO 1 2 APR 2001

Enclosures:

1. Cover Page of Published PCT International Application No. PCT/IB99/01670
2. Verification of English Translation of International Application
3. Translation of Amended Specification, Page 2 and Claims Pages 9 and 10
4. Substitute Drawing Sheet Numbers 1 through 6, Containing Figures 1-7
5. Return Receipt (Postcard)

APR 24 2001

09/807586

Mailed via Express Mail No. EL178952483US on April 12, 2001

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